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# Complementary and alternative medicine and consumer law

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*The application of consumer Law has become significant in the health sector including the provision of complementary and alternative medicine. Many legal authorities in this area deal with extreme examples of breaches of consumer law which provides a problematic image for the evidence base for this form of health care especially when high quality scientific is sought in regard to representations made. The article discusses the fact that in some contexts traditional use evidence is applied in regard to the determination of appropriate indications of use for the registration and listing of complementary and alternative medicine but this does not appear to be applied in consumer law decisions. The capacity to provide high quality scientific evidence is limited for many form of complementary and alternative medicine based upon their historical background and approach to healing. Based upon an analysis of the value obtained from scientific evidence for complementary and alternative medicine this article argues for a broader use of traditional evidence and other forms of evidence to support compliance with consumer legislation in a context of where public safety is preserved.*

## Introduction

There have been a number of examples in recent years of worrying breaches of consumer legislation in relation to misleading or deceptive conduct by CAM practitioners.[1] The regulation of CAM is important owing to its significant but underrated role in the Australian health sector. In 2007, a study found that national expenditure for CAM medicines was $4.1 billion, and that the estimated number of visits to CAM practitioners by adult Australians in a 12–month period (69.2 million) was almost identical to the estimated number of visits to medical practitioners (69.3 million).[2] In some areas of Australia, CAM practitioners providing primary care services outnumber conventional

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1 *ACCC v Allergy Pathway Pty Ltd* [2009] FCA 960; BC200907920; *ACCC v NuEra Health Pty Ltd (in liq)* (2007) ATPR (Digest) 46-273; (2007) ASAL 55-172; [2007] FCA 695; BC200703471; *Commissioner of Fair Trading, Department of Commerce v Hunter* [2008] NSWSC 277; BC200802120; I Freckelton, 'Death by Homeopathy: Issues for Civil, Criminal and Coronial Law and for Health Service Policy' (2012) 19 *Jnl of Law and Medicine* 454 at 464.

2 C C Xue et al, 'Complementary and Alternative Medicine Use in Australia: A National Population-Based Survey' [2007] (July–August) 13 (6) *Jnl of Alternative and Complementary Medicine* 643 at 643.

primary care physicians.[3] As only chiropractors, osteopaths and traditional Chinese medicine practitioners in Australia are subject to specific statutory regulation and disciplinary enforcement processes, the ability to apply disciplinary procedures to suspend or exclude other CAM practitioners from practice is generally not available.[4] In New South Wales under the NSW Public Health Act 2010, the *Code of Conduct for Unregistered Health Practitioners*[5] and provisions of the Health Care Complaints Act,[6] it is possible to grant prohibition orders or place conditions on the practice of unregistered health practitioners who are found to be in breach of the provisions of the *Code of Conduct* or consumer legislation. Similar provisions now apply in South Australia under the Unregistered Health Practitioners: Code of Conduct — Health and Community Services Complaints Regulations 2005.[7] In practice, these provisions have been used for the removal of grossly unethical practitioners and do not offer public protection for 'minor' breaches such as financial exploitation and misleading claims by practitioners.[8]

Other unregistered CAM practitioners not subject to the above regime such as homoeopaths, herbalists, naturopaths and massage therapists are self-regulated by voluntary membership of professional associations with possible disciplinary actions involving fines, reprimands, suspension or exclusion from membership.[9] Even if the most substantial penalties of suspension or exclusion are applied by these bodies, they do not require a practitioner to cease practice, though it may result in the practitioner losing access to private insurance rebates or GST exemption for their services.[10] These arrangements have sometimes been inadequate, with some professional associations refusing to deregister practitioners known to be practising unethically due to concerns that a practitioner might respond by commencing legal action in response.[11]

One means of regulating the practices of unregistered health practitioners is through consumer legislation and, in particular, through the provisions of the

3 J Wardle et al, 'Distribution of Complementary and Alternative Medicine (CAM) Providers in Rural New South Wales, Australia: A Step towards Explaining High CAM Use in Rural Health?' (2011) 19(4) *Aust Jnl of Rural Health* 197 at 199.

4 Available for registered practitioners under s 196 of the Health Practitioner Regulation National Law Act 2009 (Qld) (National Law). Some restricted acts under s 123 of the National Law prohibit a person from certain acts, such as manipulation of the cervical spine, unless specified as an appropriate practitioner. This regulation would apply to unregistered health practitioners.

5 Public Health Regulations 2012 (NSW) Sch 3.

6 Health Care Complaints Act 1993 (NSW) ss 41A, 41 AA.

7 Health and Community Services Complaints Regulations 2005 (SA) Sch 2.

8 Australian Health Ministers Advisory Council, *Consultation Paper: Options for Regulation of Unregistered Health Practitioners*, February 2011, p 31.

9 M Weir, *Law and Ethics in Complementary Medicine: A Handbook for Practitioners in Australia and New Zealand*, 4th ed, Allen and Unwin, Crow's Nest, NSW, 2011, pp 6–7.

10 Ibid, p 251.

11 For example, the NSW *Code of Conduct for Unregistered Practitioners* was developed largely in order to remove from practice a Newcastle naturopath (Paul Perret), who had faked his qualifications and had previously been convicted of fraud and armed robbery, after his association refused to deregister him for fear he may sue. This is discussed in Parliamentary *Hansard*: New South Wales, *Parliamentary Debates*, Legislative Assembly, 30 November 2005, p 161; 20388, Mr Matthew Norris, New South Wales Legislative Assembly, 2005; New South Wales Parliamentary Debates, *Hansard*, p 161: 20388.

Australian Consumer Law (ACL) under the Competition and Consumer Act,[12] which deals with misleading and unfair practices. This article focuses on the standard of evidence required in recent consumer protection decisions in regard to CAM cases. This analysis will reveal that judicial decisions in CAM cases usually reflect the scientific evidence based perspective of orthodox medicine (OM). This article will also consider whether, taking into account the healing philosophy of CAM, the need for scientific evidence to justify representations is appropriate when this perspective does not fit easily with the traditions and clinical approach of many CAM modalities.

## What is CAM?

CAM has been defined as therapies not taught in US medical schools.[13] The British Medical Association defined non-conventional therapies as 'those forms of treatment which are not widely used by orthodox health-care professions, and the skills of which are not taught as part of the undergraduate curriculum of orthodox and paramedical health-care courses'.[14] Some types of CAM are called 'alternative medicine'. This may aptly describe the clinical approach of some practitioners of modalities such as traditional Chinese medicine or homoeopathy. These modalities seek to provide an alternative to orthodox medicine as complete systems of healing not limited to a part of the body or a limited set of treatment options.[15] Complementary medicine is intended to complement orthodox medicine and is particularly applicable to a therapy like therapeutic massage. In this article the term 'complementary and alternative medicine' (CAM) will be used in an attempt to incorporate the widest possible scope for the various modalities although it is acknowledged it perpetuates the tendency to define these therapies or models of healing from the perspective of orthodox medicine.[16] Complementary and alternative medicine is applied by practitioners who specialise in one or a number of modalities as exampled by chiropractors, osteopaths, naturopaths, western herbalists, traditional Chinese medicine practitioners, homoeopaths and massage therapists.

## Application of the Australian Consumer Law to CAM

Freckelton has commented that:

> Actions brought under Australian States' fair trading legislation or by the Australian and Competition and Consumer Commission (ACCC) under the Trade Practices Act

12 Competition and Consumer Act 2010 (Cth).

13 M S Micozzi, 'Characteristics of Complementary and Alternative Medicine' in M S Micozzi (Ed), *Fundamentals of Complementary and Alternative Medicine*, Churchill Livingstone, London, 1996, p 5; D M Eisenberg, 'Advising Patients Who Seek Alternative Medical Therapies' (1997) 127 *Annals of Internal Medicine* 61 at 61.

14 British Medical Association, above n 9, pp 7–8; W B Jonas, 'Alternative Medicine-Learning from the Past, Examining the Present, Advancing to the Future' (1998) 280 *Jnl of the American Medical Association* 1616 at 1616.

15 British Medical Association, above n 9, p 7.

16 N Gevitz, 'Three Perspectives on Unorthodox Medicine' in N Gevitz (Ed), *Other Healers: Unorthodox Medicine in America*, John Hopkins University Press, Baltimore MD, 1988, p 2; M H Cohen, *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives*, John Hopkins University Press, Baltimore MD, 1998, p viii.

1974 (Cth) and now under Ch 2 of Sch 2 to the Competition and Consumer Act 2010 (Cth) have emerged as an increasingly important tool in the regulation of both registered and unregistered health practitioners.[17]

This reflects a strategy of the ACCC to focus on health practitioners and representations about health products and services in applying its regulatory function, which is expressed in the authorities discussed in this article.[18] The case law provides examples of serious misconduct by CAM practitioners characterised by very expensive treatments for serious and potentially life threatening illnesses for vulnerable patients, often involving a practitioner with doubtful or non-existent training and qualifications. These cases normally entail the application of therapies that lack any supporting evidence of efficacy or safety, often with a lack of information provided to the patient about the nature of the treatment offered and the state of scientific evidence to support the application of the therapy.[19] These circumstances typically result in breaches of consumer legislation.

Relevant sections of the ACL that arise in relation to these matters include:

**Section 18 Misleading or deceptive conduct**

A person must not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive.

**Section 29 False or misleading representations about goods or services**

A person must not, in trade or commerce, in connection with the supply or possible supply of goods or services or in connection with the promotion by any means of the supply or use of goods or services:

(a) make a false or misleading representation that goods are of a particular standard, quality, value, grade, composition, style or model or have had a particular history or particular previous use;

(b) make a false or misleading representation that services are of a particular standard, quality, value, or grade;

(g) make a false or misleading representation that goods or services have sponsorship, approval, performance characteristics, accessories, uses or benefits;

**Section 33 Misleading conduct as to the nature etc of goods**

A person must not, in trade or commerce, engage in conduct that is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose or the quantity of any goods.

**Section 34 Misleading conduct as to the nature etc of services**

A person must not, in trade or commerce, engage in conduct that is liable to mislead the public as to the nature, the characteristics, the suitability for their purpose or the quantity of any services.

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17 I Freckelton, 'Unscientific Health Practice and Disciplinary and Consumer Protection Litigation' (2011) 18(4) *Jnl of Law and Medicine* 645 at 654.

18 ACCC, *Medical, Health Service Providers Warned on Advertising*, 20 July 2000, at <http://www.accc.gov.au/content/ index.phtml/itemId/87430/fromItemId/622975> (accessed 17 June 2013). Note the recent commencement of action by the ACCC in regard to representations by a homoeopath in regard to a homoeopathic vaccine for whooping cough. See ACCC, *ACCC Takes Action over Potentially Misleading Vaccine Claims*, 21 February 2013, at <http://www.accc.gov.au/media-release/accc-takes-action-over-potentially-misleading-vaccine-claims> (accessed 17 June 2013).

19 Freckelton, above n 17, at 665.

A number of 'well-established propositions' underpin the application of the above provisions:[20]

- in considering the effect of allegedly misleading conduct on a class of persons such as consumers who may range from the gullible to the astute, the court must consider whether the 'ordinary' or 'reasonable' members of that class would be misled;
- conduct causing confusion and wonderment is not necessarily co-extensive with misleading conduct;
- there is no requirement that the impugned conduct must be intended to mislead — a contravention of the ACL's misleading conduct provisions can be established even though a party acted reasonably and honestly; and
- the words 'likely to mislead or deceive' in s 18 make it clear that it is not necessary to demonstrate actual deception to establish a contravention of that provision.

## Consumer case law and complementary medicine

One significant aspect of most of the cases discussed below is that there was little, if any, evidence provided by the defendant to support the representations made. This limits the level of guidance provided by those cases as against making representations based upon a supportable evidence base. In regard to the level of evidence made available by the defendant in this manner, the case law can be categorised as follows:

1. No evidence provided by the defendant against the plaintiff scientific evidence (*Purple Harmony*;[21] *Commissioner of Fair Trading, Department of Commerce v Perrett*;[22] *ACCC v NuEra Health Pty Ltd (in liq)*;[23] *ACCC v Jones*;[24] *Willesee Healthcare*).[25]
2. Limited evidence provided by the defendant against plaintiff scientific or professional evidence (*Advanced Allergy Elimination Pty Ltd*;[26] *Commissioner of Fair Trading, Department of Commerce v Hunter*).[27]
3. Some general scientific evidence provided by the defendant against plaintiff scientific and professional evidence (*Giraffe World*).[28]

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20 *Google Inc v ACCC* (2013) 294 ALR 404; 87 ALJR 235; [2013] HCA 1; BC201300295 at [6]–[9]. Although the High Court's primary focus in this case was on s 52 of the TPA (now s 18 of the ACL), these propositions can be extrapolated to the other misleading conduct/representation provisions in that legislation.

21 *ACCC v Purple Harmony Plates Pty Ltd* [2001] FCA 1062; BC200104454.

22 *Commissioner of Fair Trading, Department of Commerce v Perrett* [2007] NSWSC 1130; BC200708733.

23 *ACCC v NuEra Health Pty Ltd (in liq)* (2007) ATPR (Digest) 46-273; (2007) ASAL 55-172; [2007] FCA 695; BC200703471.

24 *ACCC v Jones (No 5)* [2011] FCA 49; BC201100263.

25 *ACCC v Willesee Healthcare Pty Ltd* [2011] FCA 301; BC201102045.

26 *ACCC v Allergy Pathway Pty Ltd* [2009] FCA 960; BC200907920.

27 *Commissioner of Fair Trading, Department of Commerce v Hunter* [2008] NSWSC 277; BC200802120.

28 *ACCC v Giraffe World Australia Pty Ltd* (1999) 95 FCR 302; 166 ALR 74; [1999] FCA 1161; BC9905234.

4. Scientific evidence provided by the defendant against plaintiff scientific and professional evidence (*Operation Smile (Australia) Inc*).[29]
5. Traditional evidence against plaintiff scientific and professional evidence — this has not arisen in the case law.

A significant authority dealing with misleading or deceptive behaviour relevant to complementary medicine is *ACCC v Purple Harmony Plates Pty Ltd*.[30] This matter related to the representations made in relation to a product called 'Purple Harmony plates', which came in different forms including disks, angels, phone disks and fridge fresheners. These products were said to have many and varied therapeutic benefits, including: negating the effects of electromagnetic radiation; accelerating healing; calming people; increasing health; decreasing stress levels; strengthening the immune system; treating cuts, burns, aches and pains; green thumbs to treat water and a fuel ionizer system to treat fuel and improve its efficiency.[31]

The ACCC argued that these representations made on a website and in certain publications suggested these products had performance characteristics they did not possess and were misleading or deceptive or likely to mislead or deceive,[32] contrary to ss 52 and 53(c) of the Trade Practices Act 1974 (Cth).[33] The ACCC relied upon s 51A of the Trade Practices Act[34] and argued that the representations were as to future matters that could not be substantiated.[35] This provision placed the burden of proof upon a party who had made a representation about a future matter to demonstrate that it had reasonable grounds for making the representation, otherwise the representations would be deemed to be misleading.

The court held that the defendant had represented the products possessed the performance characteristics claimed and that these representations made claims as to future matters and suggested that a person who purchased the product would derive the stated benefits from the product.[36] The defendant did not provide any substantial evidence to support the assertions made that would address the question of whether the company had any reasonable grounds for making the representations.[37] Accordingly, the representations were deemed to be misleading.[38] The court ordered injunctive relief against the respondents making these representations and required refunds to customers and corrective advertisement.[39]

Similar issues arose in *Commissioner of Fair Trading, Department of*

29 *Noone, Director of Consumer Affairs (Vic) v Operation Smile (Australia) Inc* [2012] VSCA 91; BC201202920.
30 *ACCC v Purple Harmony Plates Pty Ltd* [2001] FCA 1062; BC200104454.
31 Ibid, at [17].
32 Ibid, at [10].
33 Now s 18 and 29(G) of the ACL.
34 Now s 4(1) of the ACL.
35 *ACCC v Purple Harmony Plates Pty Ltd* [2001] FCA 1062; BC200104454 at [11].
36 Ibid, at [21]–[22].
37 Ibid, at [20].
38 Ibid, at [22].
39 Ibid, at [31].

*Commerce v Perrett*,[40] where the Commissioner sought a declaration that the defendant Perrett had engaged in misleading or deceptive conduct and conduct likely to mislead or deceive in contravention of the Fair Trading Act 1987 (NSW).[41] It was also suggested he had engaged in conduct that was liable to mislead the public as to the nature, characteristics and suitability for their purpose of certain goods in contravention of s 49 of the same legislation.[42] The Commissioner sought a restraining order in relation to these types of activities.[43]

The court dealt with the defendant's actions in relation to a number of clients, involving the use of unorthodox substances of uncertain or unknown composition, the diagnosis and treatment of acute and chronic medical conditions and the application of ointments and intravenous injections.[44] The Commissioner suggested that the defendant had represented he had an ability to treat multiple sclerosis,[45] breast cancer,[46] a thyroid condition,[47] terminal cancer, Huntington's Disease[48] and sympathetic nerve dystrophy.[49] The Commissioner also suggested the defendant made statements suggesting clients should not rely upon medical treatment and indicating he had access to knowledge and substances not normally available.[50] The *defendant was not able to present evidence* to support the representations he made about his ability to treat those ailments. The plaintiff relied upon s 41(2)[51] that placed the burden of proof upon a person who has made a representation about a future matter to demonstrate that he or she had reasonable grounds for making the representation, otherwise the representations would be deemed to be misleading. The court relied upon statements of clients, and on that basis Perrett was held to have made representations that were misleading or deceptive or likely to mislead or deceive; restraining orders were granted to stop that behaviour.[52]

In the same year as the *Perrett* decision, misleading representations in breach of the Trade Practices Act were held to have been made by the respondent company in *ACCC v NuEra Health Pty Ltd (in liq)*.[53] The

40 *Commissioner of Fair Trading, Department of Commerce v Perrett* [2007] NSWSC 1130; BC200708733.
41 Fair Trading Act 1987 (NSW).
42 Now s 33 of the Competition and Consumer Act 2010 (Cth).
43 *Commissioner of Fair Trading, Department of Commerce v Perrett* [2007] NSWSC 1130; BC200708733 at [2].
44 Ibid, at [6].
45 Ibid, at [9].
46 Ibid, at [25].
47 Ibid, at [56].
48 Ibid, at [79].
49 Ibid, at [97].
50 Ibid, at [9], [25], [56], [79], [97].
51 Now s 4(1) of the ACL which provides: 'If: (a) a person makes a representation with respect to any future matter (including the doing of, or the refusing to do, any act); and (b) the person does not have reasonable grounds for making the representation; the representation is taken . . . to be misleading.'
52 *Commissioner of Fair Trading, Department of Commerce v Perrett* [2007] NSWSC 1130; BC200708733 at [134].
53 *ACCC v NuEra Health Pty Ltd (in liq)* (2007) ATPR (Digest) 46-273; (2007) ASAL 55-172; [2007] FCA 695; BC200703471.

statements in question, which promoted NuEra's products and 'treatments' to cancer victims via the company's website, were categorised by the ACCC as the 'cure cancer representations', the 'prolong life representations' and the 'scientific support representations', and condemned by Ryan J as exemplifying 'conduct of the most reprehensible kind'.[54] In coming to this decision, his Honour was scathing of the fact that the *respondent had not adduced any evidence* to contradict or 'palliate' the case presented by the ACCC.[55]

In *ACCC v Jones*,[56] the ACCC instituted proceedings against Darryl Peter Jones in respect of alleged contraventions of the Trade Practices Act.[57] The ACCC claimed that a website Mr Jones maintained and a publication authored by him, entitled 'The Truth about Overcoming Cancer', contained representations that were misleading or deceptive:

> The Darryl Jones Health Resolution Centre methodology is based on the resolution of life-threatening diseases without dispensing pharmaceutical drugs, advocating radium therapy, surgery, or harmful chemotherapy — focusing instead on a three-step Triune Wellness Offensive — utilizing nutrition, exercise, and vitamins, along with close, professional, personal accountability.
>
> The Darryl Jones Health Resolution Centre — committed to your total victory over modern day life-threatening diseases — with time-proven personal strategies empowering you with the tools you need for a prolonged life, greater health, and real hope for the future.[58]
>
> The crux of the matter is that Cancer Loves Glucose and glucose is easily obtainable from many of the vast majority of foods that we ingest daily. So to take away its major source of nutrition will deprive it of 'its life source' and therefore compromise its ability to persist and grow. This access to Glucose helps to explain the awesome rise in new cases of cancer, at a rate which is unprecedented at any time in our history. It is a modern day epidemic![59]

On behalf of the ACCC, physician Dr Snyder FRACP indicated that there was either limited or no scientific evidence for these types of representations.[60] On the balance of this evidence, there was a finding by the court that the statements were misleading or deceptive.[61] Although this matter was an interlocutory injunction that did not involve a full statement of claim, there was little discussion of the connection between the evidence adduced by the ACCC and the statements that were impugned with the ACCC's request to grant an injunction seemingly readily accepted once the report of Dr Snyder was provided. This would indicate that the scientific report was accepted as the basis of the finding of misleading or deceptive conduct apparently in the absence of any substantive evidence from the defendant.

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54 Ibid, at [8], [6].
55 Ibid, at [6].
56 *ACCC v Jones (No 5)* [2011] FCA 49; BC201100263.
57 Ibid, at [1].
58 Ibid, at [2].
59 Ibid, at [5]. The issue here most likely was the absolutist language used. This suggests the need to not represent beyond the data or be moderate in your conclusions etc and 'reference to Emerging' evidence etc.
60 Ibid, at [8].
61 Ibid, at [10].

In *ACCC v Advanced Allergy Elimination Pty Ltd*,[62] an action was commenced by the ACCC against the respondent Advanced Allergy Elimination (AAE), which operated clinics for the diagnosis and treatment of allergies. The methods by which AAE diagnosed and treated allergies included testing for and identifying a person's specific allergies using a muscle strength indicator technique and treating allergies by using a technique based on positive and negative conditioning.[63] AAE advertised on an internet website, on radio, in newspapers and in brochures given to clients, prospective clients and other interested persons.[64]

The ACCC alleged that certain statements published on the website and contained in the advertisements were in breach of the Trade Practices Act.[65] The impugned statements related to the ability of AAE to test for and identify a substance to which a person was allergic, that it could cure or eliminate virtually all allergies or allergic reactions, that it could successfully treat a person's allergies or allergic reactions and that its treatment was safe or involved low risk.[66] These allegations were upheld based upon evidence provided by a Professor Douglass, the Head of the Allergy, Asthma and Clinical Immunology Service at the Alfred Hospital, who suggested there was little or no scientific evidence for the statements impugned in the action.[67] The assumption appeared to be that, as there was limited scientific evidence for the statements, accordingly they were misleading or deceptive.

In a similar factual circumstance in *ACCC v Willesee Healthcare Pty Ltd*,[68] the court determined that representations by the respondent about treating allergies through kinesiology and acupressure and thereby being able to cure or eliminate all, or virtually all, allergies or allergic reactions were misleading and deceptive representations, also based upon the expert evidence of Professor Douglass.[69] This conclusion was reached *in the absence of other evidence* to the contrary.

In *Commissioner of Fair Trading, Department of Commerce v Hunter*,[70] an injunction was sought against Hunter, who practiced as a naturopath and medical herbalist. The primary focus of the case was in relation to his advertising of 'live blood analysis', which was said to allow diagnosis of ailments instantly and to assist in the treatment of such illnesses that the Commissioner suggested was a misleading representation under the terms of the Fair Trading Act.[71] Also of concern in this matter were the representations made about the qualifications of Mr Hunter and his ability to diagnose and treat serious health conditions.[72]

Mr Hunter used the titles 'Dr', 'Doctor of Natural Medicine' and PhD in

62 *ACCC v Allergy Pathway Pty Ltd* [2009] FCA 960; BC200907920.
63 Ibid, at [1].
64 Ibid.
65 Ibid.
66 Ibid, at [2].
67 Ibid, at [4].
68 [2011] FCA 301; BC201102045.
69 Ibid, at [33].
70 [2008] NSWSC 277; BC200802120.
71 Fair Trading Act 1987 (NSW) ss 42,44 (e) and (f) and 50 . . .
72 *Commissioner of Fair Trading, Department of Commerce v Hunter* [2008] NSWSC 277; BC200802120 at [2].

advertisements as well as words that could suggest he was a medical doctor.[73] As Mr Hunter was not a medical doctor, these representations were considered to be misleading or deceptive representations.[74] Also deemed to be misleading or deceptive was the representation that he was competent to treat serious illnesses such as high blood pressure and a list of other conditions.[75] Evidence was adduced from Professor Eva Raik, a haematologist with extensive qualifications and experience about the efficacy of live blood analysis and the difficulty in ascertaining medical conditions or making therapeutic decisions or diagnosis from that type of study.[76] There was *limited evidence produced by Hunter* in relation to the evidence basis for this therapy. The court found, on the basis of the expert evidence, that the representations in regard to the value of live blood analysis were misleading or deceptive or likely to mislead or deceive.[77] The court ordered that Mr Hunter be permanently restrained from carrying on a business or in any way providing in trade and commerce naturopathy, medical herbalism, herbalism, iridology, hydrotherapy, sports medicine, osteopathy and blood analysis.[78]

The case *ACCC v Giraffe World*[79] involved the marketing of an 'ion mat' (the mat) by the first respondent Giraffe World. The mat or mattress was connected to a source of electricity. There is nothing in the judgment to suggest this item had been listed as a therapeutic device under the Therapeutic Goods Act.[80] The ACCC alleged that Giraffe World made misrepresentations in contravention of ss 52 and 53(c) of the Trade Practices Act,[81] in suggesting that as a result of its emission of negative ions the mat benefited the health of persons who slept on it.[82] Giraffe World provided some expert testimony to support these assertions, including evidence from an experienced naturopath,[83] a chiropractor[84] and an academic engineer.[85] There was also reference to a published article by a Japanese professor about the impact of these types of equipment on the human body, though without suggesting any particular health benefits.[86]

The ACCC adduced evidence from an array of medical doctors and university experts in physics about the performance and impact of the mat. The judge concluded that the weight of the evidence provided by the ACCC suggested he should prefer the view of the ACCC, and this resulted in the

73 He also misrepresented his alma mater (Medicina Alternativa — an unaccredited diploma mill) as MA, which was suggested could have reasonably been interpreted as meaning a Master of Arts. Even the PhD was deemed as misleading, as it was not a recognised qualification.
74 Ibid, at [35].
75 Ibid, at [7].
76 Ibid, at [51].
77 Ibid, at [54].
78 Ibid, at [131].
79 (1999) 95 FCR 302; 166 ALR 74; [1999] FCA 1161; BC9905234.
80 Section 41BD (describe what legislation stipulates).
81 Now s 18 and s 29(g) of the ACL.
82 *ACCC v Giraffe World Australia Pty Ltd* (1999) 95 FCR 302; 166 ALR 74, 77; [1999] FCA 1161; BC9905234 at [2].
83 Ibid, at [127].
84 Ibid, at [129].
85 Ibid, at [130].
86 Ibid.

court determining the representations were misleading or deceptive.[87] This case process further entrenches the view that statements made about a piece of equipment should be supported by scientific evidence, otherwise there is a possibility of a finding of a breach of consumer legislation.

A significant authority that deals directly with the issue of what type of evidence is required to avoid a finding that an activity is deemed misleading or deceptive is *Noone, Director of Consumer Affairs Victoria v Operation Smile*.[88] Four respondents (collectively, Operation Smile) operated the 'Hope Clinic', described as a complementary medicine centre specialising in the treatment of cancer. Operation Smile's website described the treatments offered at the Hope Clinic for a long list of serious medical conditions such as cancer and HIV and contained statements relating to the efficacy of these treatments based upon peer reviewed and published methods of cancer treatment;[89] it claimed that the techniques used at the clinic included state-of-the-art medical technology and subtle energy therapies such as homoeopathy and acupuncture.[90] The Director of Consumer Affairs alleged that Operation Smile engaged in misleading or deceptive conduct in trade or commerce contrary to s 9(1) of the Fair Trading Act 1999 (Vic)[91] on the basis that the statements falsely represented that the treatments offered by Operation Smile treated cancer effectively based upon scientific evidence.[92] Operation Smile admitted these statements were made but denied that they were misleading or deceptive.[93]

Interestingly, at first instance Pagone J held that the Operation Smile treatments did not have the support of conventional science and, according to conventional science, were of no benefit to cancer sufferers.[94] Nevertheless, his Honour determined that readers of the statements would understand them, in their context, as mere expressions of opinion and as claiming no support from conventional medicine or science leading to a finding that the activity considered was not misleading or deceptive.[95] On appeal, the Court of Appeal did not endorse this view and the other views expressed by the trial judge in relation to the statements made by the Hope Clinic.

The Court of Appeal held the net effect of the statements was that the treatments offered were as scientifically based and rigorously tested as those of conventional medicine based upon an assessment of the whole of the context within which the statements were made.[96]

87 Ibid, at [114].
88 [2012] VSCA 91; BC201202920.
89 Ibid, at [56].
90 Ibid, at [67].
91 Now s 18 of the ACL.
92 *Noone, Director of Consumer Affairs Victoria v Operation Smile (Australia) Inc* [2012] VSCA 91; BC201202920 at [52].
93 Ibid, at [61], [113].
94 *Noone, Director of Consumer Affairs Victoria v Operation Smile (Australia) (No 2)* [2011] VSC 153; BC201102208 at [16].
95 Ibid, at [52], [65], [77], [81].
96 *Noone, Director of Consumer Affairs Victoria v Operation Smile (Australia) Inc* [2012] VSCA 91; BC201202920 at [59].

> As appears from what is set out above, the context included the claim that the Hope Clinic adopted an integrated approach to the treatment of chronic illness combining state-of-the-art medical technology with alternative therapies; the explicit description of Hope Clinic therapies as the best scientific complementary medicine; the ostensibly scientific names ascribed to the therapies offered by the Hope Clinic, such as 'photo dynamic therapy', 'Holt Microwave therapy' 'Oxygen therapy' and 'Biolife electrotherapy'; the assertion as to practitioners of complementary medicine not hesitating 'to employ conventional medical practices'; the explicit assertion that the Hope Clinic's combination of alternative treatments with conventional medicine would optimize a patient's treatment plan; and the surely very remarkable claim that: The network of colleagues who make up this institute are committed to reading and researching all published information. We contact scientists and physicians all over the world to learn at first hand from these eminent colleagues in hospitals, universities and laboratories.[97]

Although the Court of Appeal allowed the appeal and held that the statements discussed in the case were misleading or deceptive, this decision is significant in that it indicated that, if precision is applied to statements made which provide clarity for the reader about the basis of the evidence to support the statements made that a breach of the misleading or deceptive conduct prohibition might be avoided.

## How have courts dealt with the provision of scientific evidence?

Although in most of the above cases there was limited, if any, substantive evidence to justify the representations made, the unexpressed assumption from these cases is that it is incumbent to provide high quality scientific evidence for the representations, otherwise a finding of misleading or deceptive conduct is easily made. This assumption is not applied in non-health related matters involving misleading or deceptive conduct.[98] It seems in all cases involving health practices that this form of evidence is required. Freckelton acknowledges that members of the general public are entitled to hold views that do not accord with scientific orthodoxy as long as they do not cause harm to others. Freckelton suggests:

> there is a constructive role for the law in preventing unscientific health practices so that vulnerable patients are not harmed or at least in regulating how such practices are advertised so that their lack of scientific legitimacy, assessed by the reference point of evidenced-based practice, is made unequivocally apparent to prospective patients so that representations based upon them will not be false, misleading or deceptive. If an accurate, evidence-based picture is given of the unlikelihood of practices or treatments having a beneficial effect, or the likelihood of their having a counter-therapeutic outcome, from the perspective of conventional science, then patients can make their own informed decisions as to whether to submit to such practices and treatments. However, the power imbalance in the practitioner-patient

97 Ibid.
98 Refer to case law below.

> relationship always has the potential to militate against the real exercise of autonomy in such circumstances and can lead to dangerous reliance upon spurious and exploitative health practice.[99]

There is not a lot to disagree with in this approach. However, as discussed below there is a case for a greater acknowledgement in this context of traditional evidence and other forms of scientific evidence to determine whether a CAM practitioner is being misleading or deceptive in his or her representations.

Is there an arguable basis to require scientific evidence in relation to serious illnesses where the practitioner is undertaking the role of primary health practitioner?[100] Does the strict test apply to every statement, representation word or gesture by all practitioners to every client?

Under current circumstances it is not practical to require scientific evidence for every statement by a CAM practitioner, and the law generally does not require this in other contexts.[101] When determining whether a practitioner was negligent in statements made, it is relevant to consider the tort of negligent misstatement which aims to redress any economic loss from that statement.[102] Negligent misstatement, is a species of the tort of negligence, is arguable when a party who has a special skill or competence or in the course of business assumes responsibility for the accuracy of a statement, advice, information or an opinion to another party in circumstances where the other person reasonably relied upon the advice, information or opinion and as a result a duty of care arises in regard to that advice.[103] The first person may be liable for economic loss or damage caused if the advice, information or opinion was given negligently. Reference is necessarily made to peer opinion based upon the terms of the civil liability legislation in the case of a person deemed a 'professional'[104] or, if not applicable, under the common law test that suggests considering the acts of a reasonably competent practitioner.[105] Should these tests also hold for statements and even advertisements of CAM products or services?

Most of the cases discussed above involve entities advertising health claims in relation to supposedly therapeutic devices (eg, ion mats),[106] persons making spurious and completely baseless claims with no or very little evidence[107]

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99 Freckelton, above n 17, at 645.

100 Cancer Council Australia, *Position Statement: Complementary and Alternative Therapies*, 18 April 2013, at <http://wiki.cancer.org.au/prevention/Position_statement_-_Complementary_and_alternative_therapies> (accessed 17 June 2013).

101 Refer to below: eg, *Olivaylle Pty Ltd v Flottweg AG* (2009) 255 ALR 632; [2009] FCA 522; BC200904211.

102 *Hedley Byrne and Co Ltd v Heller* [1964] AC 465; [1963] 2 All ER 575; [1963] 3 WLR 101; [1963] 1 Lloyd's Rep 485.

103 Barker et al, *The Law of Torts in Australia*, 5th ed, Oxford University Press, Melbourne, 2012, p 486.

104 Civil Liability Act 2003 (Qld) s 22.

105 *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118; [1957] 1 WLR 582; (1957) 1 BMLR 1 per Mc Nair J.

106 *ACCC v Giraffe World Australia Pty Ltd* (1999) 95 FCR 302; 166 ALR 74; [1999] FCA 1161; BC9905234 at [2].

107 *Commissioner of Fair Trading, Department of Commerce v Perrett* [2007] NSWSC 1130; BC200708733.

involving clients who were being treated for serious illnesses[108] and sometimes involving an abject failure to refer on to an orthodox medicine practitioner at all or in a timely fashion.[109]

Is it appropriate to apply a requirement of scientific evidence to CAM, which based on its procedures and traditions does not derive from an OM scientific evidence base? Is it appropriate to apply OM scientific evidence to CAM in regard to representations when in most cases there is no such availability when well based traditional evidence may be available?

Traditional medicine concepts are being increasingly incorporated into international standards. For example, the World Health Organization is incorporating traditional medicine classifications into the latest version of the International Classification of Diseases (ICD-11),[110] which is the international gold standard in reporting and defining disease; Standards Australia is currently involved in formulating international (ISO) standards for traditional Chinese medicine.[111] As such it would follow that these standards should also be considered when evaluating CAM with a traditional evidence base.

It is often acknowledged that CAM has an appropriate niche when dealing with self-limiting or chronic illness.[112] In regard to the treatment of serious illness, this needs to be dealt with carefully and aimed at dealing primarily with symptoms rather than cures. This is acknowledged, for example, in cl 5 of the *New South Wales Code of Conduct for Unregistered Practitioners*. Most CAM practitioners are dismayed by the activities of unprofessional CAM practitioners as are the critics of CAM. CAM practitioners should be aware of the limitations of their therapy. Any action in negligence against a CAM practitioner will refer to peer opinion, which will often not rely upon scientific evidence but may involve traditional evidence or anecdotal evidence or 'lower' forms of evidence in terms of the measures applied by orthodox medicine.[113] It is suggested that on that basis there is room to apply a more flexible application of evidence to consumer issues involving CAM practitioners.

When considering the level of scientific evidence for CAM, it should be understood that OM is not compliant in the practice of evidence based medicine (EBM). It has been suggested that half of conventional medical treatment is of unknown effectiveness, with only 11% definitively beneficial and 24% probably beneficial; additionally it is estimated that most of Australian Medicare's 5000 items have not been comprehensively assessed for safety, effectiveness or cost-effectiveness.[114] Moreover, publication bias and

108 *Commissioner of Fair Trading, Department of Commerce v Hunter* [2008] NSWSC 277; BC200802120.

109 Ibid.

110 At <http://www.who.int/classifications/icd/revision/en/> (accessed 17 June 2013).

111 Standards Australia — international (ISO) standards for traditional Chinese medicine; P F Gao and K Watanabe, 'Introduction of the World Health Organization Project of the International Classification of Traditional Medicine' (2011) 9(11) *Jnl of Chinese Integrative Medicine* 1161.

112 M Weir, *Alternative Medicine: A New Regulatory Model*, Australian Scholarly Publishing, Melbourne, 2005, p 107.

113 *Shakoor v Situ* [2000] 4 All ER 181; [2001] 1 WLR 410.

114 R Moynihan, 'Assaulting Alternative Medicine: Worthwhile or Witch Hunt?' (2012) *BMJ*; 344:1075.

the preponderance of unpublished trials have also recently brought into question the usefulness of relying on clinical trial evidence alone.[115]

Additionally, the complexities of clinical practice may produce a divergent evidence base, which does not lend itself easily to simplistic interpretation of positive or negative evidence. Although often viewed as the gold standard of evidence, meta-analyses of the same therapies may produce different results depending on exclusion and inclusion criteria for studies, which may be subjective. For example, using the same search strategies, homoeopathy's effect can be found to be both better than, no better than, or even worse than placebo.[116] When clinical trials are used, the evidence for homoeopathy is equivocal at best. However, observational and population health studies consistently show demonstrable improvement in patients from homoeopathic treatment.[117] Additionally, observational or population-based studies may demonstrate effect for treatments that are not supported by clinical trials. Primary care itself provides a useful case study for this phenomenon, with clinical trial data suggesting it is less cost-effective or clinically effective than specialist care, whilst population-based data shows it to be the most effective method through which to improve population health outcomes.[118] Such divergent results highlight legitimate differing interpretations of clinical evidence, which need to be considered in weighing evidence.

The marketing of CAM goods and services could incorporate an approach that applies the following parameters:

a. Acknowledging where the evidence base is traditional in nature.
b. Acknowledging where the evidence base is derived from professional practice well accepted by a modality.
c. Acknowledging where the evidence is based on scientific evidence.
d. Acknowledging where the evidence base is a combination of the above.
e. A limitation on advertising of treatments for serious illnesses.
f. An obligation to refer to orthodox medicine when the condition does not resolve.

This process is recognised in regard to therapeutic goods under the *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* (guidelines).[119] The guidelines provide the parameters for what may be stated in advertising of pharmaceutical and CAM products directed towards consumers. The guidelines do permit reference to traditional evidence. If it is

115 I Chalmers, P Glasziou and F Godlee, 'All Trials Must Be Registered and Results Published' (2013) *BMJ* 346:f105.

116 R Lüdtke and A L Rutten, 'The Conclusions on the Effectiveness of Homeopathy Highly Depend on the Set of Analysed Trials'(2008) 61(12) *Jnl of Clinical Epidemiology* 1197.

117 C M Witt et al, 'Homeopathic Medical Practice: Long-term Results of a Cohort Study with 3981 Patients' (2005) 5(115) *BMC Public Health*, at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1298309/> (accessed 17 June 2013); C M Witt et al, 'How Healthy Are Chronically Ill Patients after Eight Years of Homeopathic Treatment? Results from a Long term Observational Study' (2008) 8(413) *BMC Public Health* <http://www.biomedcentral.com/1471-2458/8/413> (accessed 17 June 2013).

118 K Stange and R Ferrer, 'The Paradox of Primary Care' (2009) 7(4) *Annals of Family Medicine* 293.

119 Department of Health and Ageing, Therapeutic Goods Administration, Australian Government, *Guidelines for Levels and Kinds of Evidence to Support Indications and*

desired to make a claim in relation to registered or listed products, there are different levels of evidence required under the guidelines.

To make an indication or claim based on evidence of traditional use, sponsors must first assess the level of the evidence supporting the claim.

If you hold one of the following four sources of evidence, you hold general level evidence:

1. TGA-approved Pharmacopoeia.
2. TGA-approved Monograph.
3. Three independent written histories of use in the classical or traditional medical literature.
4. Availability through any country's government public dispensaries for the indication claimed.

If you hold two of the above sources of evidence, you hold medium level evidence.[120] If you hold medium level evidence, you can make medium level indications and claims, providing the evidence supports those indications/claims. Medium level indications/claims include indications/claims relating to:

- Health enhancement;
- Reduction of risk of a disease/disorder/condition;
- Reduction in frequency of a discrete event;
- Aids/assists in the management of a named symptom/disease/disorder/condition;
- Relief of symptoms of a named disease, disorder or condition.[121]

Medium and general level indications and claims may only be made for minor, self-limiting conditions. Serious diseases or disorders may not be mentioned in medium or general level indications/claims.[122]

## Consumer law in non-CAM professional contexts

In considering the way in which the legal concept of misleading or deceptive conduct is determined and the role that scientific evidence plays in this process, it is helpful to examine how this issue is dealt with in non-CAM professional contexts. As noted above, the lack of scientific evidence for CAM based therapies has in a number of cases resulted in a finding that a representation is misleading or deceptive. As the option of ceasing all representations in regard to clinical services and substances is not a practical option, the necessity arises for CAM practitioners and manufacturers to clarify how representations can be made that do not breach the ACL and/or suggesting required changes to the law in this area.

The ACL is not prescriptive of the evidence required to prove misleading or deceptive conduct. Typically, questions of proof in this area will be resolved by the application of the general principles of the law of evidence and 'on the

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*Claims: For Non-Registerable Medicines, Including Complementary Medicines, and Other Listable Medicines*, Version 1.1, April 2011, at <http://www.tga.gov.au/pdf/cm-evidence-claims.pdf> (accessed 17 June 2013).

120 Ibid, p 5.

121 Ibid, pp 6–7.

122 Ibid, p 7.

balance of probabilities'. Whether a particular representation will be held to be 'misleading or deceptive' is always a complicated question, but more so where the representation is open to a complex or controversial interpretation. While it is likely in this setting that expert evidence will be adduced as to the truth or falsity of the representation, the courts have made it clear that the question is ultimately one 'for the tribunal of fact and . . . not . . . for any witness to decide'.[123] The treatment of expert evidence by the courts, particularly in the context of the ACL, remains a vexed issue in Australia. This issue is compounded in relation to CAM, where expert witnesses may not possess the scientific or academic pedigrees of their counterparts in OM.

A leading case in this area is *Tobacco Institute v AFCO*.[124] Here the Australian Federation of Consumer Organisations (AFCO) claimed that advertisements containing representations suggesting there was little or no scientific evidence that passive smoking was responsible for negative health outcomes for non-smokers were misleading or deceptive under s 52 of the Trade Practices Act.[125] The plaintiff and defendant submitted scientific and health professional evidence to the court.[126] This case accordingly required consideration of how best to deal with conflicting scientific and professional evidence in the context of health issues. At first instance the judge proceeded to compare and contrast the differing sets of evidence to determine which evidence should be preferred.[127] As he favoured the evidence submitted by the plaintiff, judgment was given to the plaintiff.[128] The defendant appealed to the Full Court of the Federal Court. The court upheld the finding that the representations were misleading or deceptive.[129] The court held that where there were two sides to a scientific debate it was not necessary for a judge to decide which argument was to be preferred, rather whether the representation was misleading.[130] As the court determined that there was scientific evidence of the negative impact of passive smoking and more than 'little' scientific evidence of this, the representation was considered misleading or deceptive.[131]

Also of interest, albeit in the context of an engineering dispute, is *Olivaylle Pty Ltd v Flottweg AG*.[132] In this case, Olivaylle entered into a contract with Flottweg for the supply of an olive oil production line. Olivaylle asserted that the production line was defective because it failed to comply with alleged contractual specifications.[133] They also alleged that Flottweg had been

123 *Interlego AG v Croner Trading Pty Ltd* (1992) 39 FCR 348 at 387; 111 ALR 577; 25 IPR 65; BC9203904.

124 *Tobacco Institute of Australia Ltd v Australian Federation of Consumer Organisations Inc* (1992) 38 FCR 1; 111 ALR 61; 24 IPR 529; BC9203820.

125 Now s 18 of the ACL.

126 *Tobacco Institute of Australia Ltd v Australian Federation of Consumer Organisations Inc* (1992) 38 FCR 1; 111 ALR 61; 24 IPR 529; BC9203820.

127 Ibid.

128 Ibid.

129 Ibid.

130 Ibid.

131 Ibid.

132 *Olivaylle Pty Ltd v Flottweg AG (No 4)* (2009) 255 ALR 632; [2009] FCA 522; BC200904211.

133 Ibid, at [34].

misleading or deceptive in representing the capacity of the production line.[134] Flottweg denied that the production line was defective in the ways alleged and alternatively argued that it had reasonable grounds for such representations.[135]

Logan J determined the representations asserted by Flottweg were made on a reasonable basis because Flottweg had relied on company experience and knowledge, the assessments of qualified and experienced consultants and certified testing results of an independent authority.[136] Flottweg had considerable 'corporate knowledge and experience' arising from 40 years of providing equipment.[137] Logan J found that both witnesses for Flottweg had 'high tertiary engineering and trade qualifications and relevant experience'.[138]

Logan J took note of the fact that Flottweg's reliance on the assurances by a Mr Nieuwkerk, who had tertiary qualifications in engineering and considerable experience in applied engineering in relation to nitrogen flushing of industrial equipment, was not misplaced or uncritical, and Mr Nieuwkerk had the qualifications and experience to make such assurances.[139] Logan J found that Flottweg had reasonable grounds to make the representations.[140]

From engineering to plumbing — another case to consider is *Plastec Australia Pty Ltd v Plumbing Solutions and Services Pty Ltd.*[141] Here, the applicant Plastec carried on the business of designing, manufacturing and selling plastic plumbing pipes and pipe-fittings, some of which are used in plumbing and draining systems. Plastec alleged that the respondent Mr Martin engaged in misleading or deceptive conduct by distributing communications containing 17 representations that Plastec contended were not true.[142] The representations broadly suggested that Plastec's products did not perform as required by relevant standards and in relation to their functionality.[143]

Mr Martin sought to support his view by reference to his understanding of the molecular bonding properties of the materials used, the chemical properties of solvents and the nature and scope of the tests that he believed should have been used to determine the long term fitness for purpose of the fittings.[144] Mr Martin called no other evidence in support of his case. Plastec objected to the evidence of Mr Martin on the basis that he was not a polymer chemist and, therefore, could not give expert opinion evidence concerning the molecular bonding properties or particular joining methodologies and properties of chemical solvent.[145]

Plastec called a substantial body of evidence to support its allegations.[146] Greenwood J accepted the evidence of Plastec and found that Mr Martin had

134 Ibid, at [36].
135 Ibid, at [37].
136 Ibid, at [224].
137 Ibid, at [224(a)].
138 Ibid, at [224(b)].
139 Ibid, at [103].
140 Ibid, at [222].
141 *Plastec Australia Pty Ltd v Plumbing Solutions and Services Pty Ltd* [2012] FCA 5; BC201200046.
142 Ibid, at [4].
143 Ibid.
144 Ibid, at [10].
145 Ibid, at [16].
146 Ibid, at [185].

no basis on which to represent the assertions he had made regarding Plastec products.[147]

Greenwood J held that all of the statements made by Mr Martin were misleading or deceptive as Mr Martin did not have a rational foundation to represent them.[148] Greenwood J was not satisfied that Mr Martin as a retired plumber had the necessary expertise in a relevant discipline to form and give evidence of an opinion regarding the functionality of Plastec fittings.[149] He further stated that even if Mr Martin's practical experience in the plumbing industry and other roles were sufficient to provide him with a basis to form an opinion surrounding the functionality of Plastec fittings, as his opinion failed to address the body of data demonstrating compliance with Australian Standards his evidence could not be preferred over the evidence of Plastec demonstrating compliance.[150]

Rounding out this discussion is *Tetra Pak Marketing Pty Ltd v Musashi Pty Ltd*,[151] a case involving Tetra Pak, which manufactures and sells packaging material for liquid food, and Musashi, which manufactures and sells sports supplements. The parties came into conflict when Musashi created a brochure for one of its products, 'P30', and within the document made a number of representations regarding Tetra Pak products — namely, that Tetra Pak packaging was made from aluminium, that aluminium can be toxic if ingested, and that the aluminium in Tetra Pak packaging could migrate into food over time and, if ingested, aluminium causes bodily injury.[152]

The key issue before the court was whether Musashi had reasonable grounds for these assertions.[153] Musashi provided as evidence all of the material it had in its possession and had relied upon when making the statements. The material consisted of:

1. Seven pages of abstracts of 14 items that had appeared in scientific journals, preceded by the words 'there are a number of papers outlining health problems and aluminium';[154]
2. Web pages consisting of profiles of individual scientists and a list of publications by P F Zatta, who had research interests in aluminium;[155] and
3. Web pages containing lecture note summaries for a lecture titled 'Aluminium Toxicity in Plants'.[156]

Dr Trevor Mark Florence, an analytical chemist, gave evidence on behalf of Tetra Pak. It was the opinion of Dr Florence that none of the evidence supported the contention that substances contained in Tetra Pak packaging

147 Ibid, at [186].
148 Ibid, at [368].
149 Ibid, at [387].
150 Ibid, at [16].
151 *Tetra Pak Marketing Pty Ltd v Musashi Pty Ltd* [2001] FCA 1269; BC200105345.
152 Ibid, at [32].
153 Ibid, at 12.
154 Ibid, at [71].
155 Ibid, at [72].
156 Ibid, at [73].

have aluminium concentrations that are high enough to cause toxicity or that aluminium could leak into products contained in such packaging.[157]

Based on the evidence provided by Dr Florence, the material supplied by Musashi and Musashi's failure to show that there was any other evidence upon which it relied, apart from the documents, when making the representations, Katz J held that Musashi did not have reasonable grounds to make the assertions. Katz J focused solely on the absence at the relevant time of any information that would have provided reasonable grounds for Musashi to make the statements.[158] The court held Musashi had not established a reasonable basis; it was not necessary for the court to consider whether those assertions were scientifically true or false.[159]

These cases involving misleading or deceptive conduct in connection with health related (or tangentially health related) matters, but not focused on health therapy, suggest that courts will accept the opinions of well-credentialed experts in their field as relevant expert evidence and that scientific evidence is not necessarily required to determine whether a party has a proper basis for a representation. Also noteworthy is the fact that industry experience was a relevant consideration for determining the reasonableness of a representation, especially in the absence of well-founded scientific evidence.

## Is a different level required for CAM in consumer law cases?

When dealing with claims of misleading representations in advertising or in the course of practice by health practitioners, the case law suggests that these claims are assessed based upon the need for high quality scientific evidence. This is no doubt reflective of a view that when dealing with health matters there is a need for good evidence to avoid personal injury. It is increasingly an aspect of the role of government to support societal expectations and, in particular in relation to healthcare, to focus on regulation based upon the assumed rationality of science.[160] Government will tend to rely upon scientific evidence as a means to justify budgetary decisions in regard to resource allocation.[161] But is the use of scientific evidence necessarily the best evidence in all contexts (such as in CAM), and is it appropriate that the emphasis is upon scientific evidence?

There is a good basis to argue that the use of scientific evidence is based upon the hegemony enjoyed by OM in relation to health matters based upon a specific type of healing that focuses on reductionist 'body as a machine' concepts of healthcare.[162] Foucault referred to it as the 'medical gaze' whereby the medical doctor separates the body from person.[163] Orthodox medicine derives from the scientific model and encourages the type of

157 Ibid, at [78].
158 Ibid, at [84]–[85].
159 Ibid, at [86].
160 I Iyioha, 'Law's Dilemma: Validating Complementary and Alternative Medicine and the Clash of Evidential Paradigms' (2011) 8 *Evidence-based Complementary and Alternative Medicine* 1 at [34].
161 Ibid.
162 Weir, above n 112, p 70.
163 M Foucault, *The Birth of the Clinic* Routledge, 1963.

scientific research preferred by OM. Orthodox medicine increasingly defines knowledge on the basis of the results of clinical research rather than a reliance upon observation or other empirical information that might be considered part of the 'art' of the practice of medicine.[164] Complementary and alternative medicine relies upon very different principles and does not necessarily comply with this OM model.[165] The OM perspective on evidence is based upon a Western type of thinking that obscures health outcomes only evident from a non-Western or traditional perspective.[166]

The type of scientific study sought by OM is a randomised controlled trial (RCT):

> RCT is a study design in which individuals are randomly allocated to at least two groups, usually called the 'study' and the 'control' group. One group is subject to a standardized experimental intervention, while the other group receives placebo or standard treatment. The results are assessed by rigorous comparison of the outcome(s) in the study and control groups respectively. In order to limit bias, group allocation maybe concealed to participants (ie blinding). RCTs are generally considered as the most scientifically rigorous method of assessing the efficacy of an intervention and, thus, represent the 'gold standard'.[167]

Some consider that the use of blinding and placebo control is not integral to RCT design and can be deleted, though this may open the study to criticism.[168] The use of randomised double blind controlled trials may be considered the 'gold standard' of scientific evidence but there are limitations on the value of this type of evidence that have been widely acknowledged in regard to its application to CAM.[169] This type of evidence does not necessarily fit well with the type of healing philosophy applied by CAM and may suggest that the focus on scientific evidence may not be supportable and applies an unduly onerous and misplaced burden on CAM to justify efficacy and safety claims.[170] However, the limitations of randomised controlled trials are not solely related to CAM, with their limitations being increasingly acknowledged in OM.[171] Even when not relying on RCTs, there exist a number of

164 M R Tonelli and T C Callahan, 'Why Alternative Medicine Cannot Be Evidenced-Based' (2001) 76(12) *Academic Medicine* 1213 at 1214.

165 K F Schaffner, 'Assessments of Efficacy in Biomedicine: The Turn toward Methodological Pluralism' in D Callaghan (Ed), *The Role of Complementary and Alternative Medicine, Accommodating Pluralism*, Georgetown University Press, Washinton DC, 2002, p 7.

166 Ibid, pp 5–6; W B Jonas, 'Evidence, Ethics, and the Evaluation of Global Medicine' in Callaghan, ibid, p 122.

167 M J Verhoef, 'Assessing Efficacy of Complementary Medicine: Adding Qualitative Research Methods to the "Gold Standard"' (2002) 8(3) *Jnl of Alternative and Complementary Medicine* 275 at 275–6; Tonelli and Callahan, above n 164, at 1214.

168 Verhoef, ibid, at 276.

169 Ibid, at 275; N Black, 'Why We Need Observational Studies to Evaluate the Effectiveness of Health Care' (1996) 312 *British Medical Jnl (International Edition)* 1215.

170 J Wardle and D Seely, 'The Challenges of Traditional, Complementary and Integrative Medicine Research: A Practitioner Perspective' in J Adams et al (Eds), *Traditional, Complementary and Integrative Medicine — An International Reader*, Palgrave Macmillan, Basingstoke, UK, 2012, p 268.

171 Moynihan, above n 114.

conventional rigorous research methodologies that may offer a more clinically accurate evaluation tool for CAM, particularly in public health and health services research.[172]

The focus on randomised controlled trials has led to a denigration of non-experimental methods, suggesting that any other approach is invalid.[173] Randomised controlled trials may not be useful where the number of subjects is not large enough to measure infrequent adverse events or rare adverse events; they do not deal well the health outcomes that may only arise far in the future.[174] In addition, if the effectiveness of a treatment depends upon a subject's active participation, which is generally a significant issue in regard to the self-help component of many CAM modalities such as naturopathy, or is reliant on a subject's beliefs and preferences, the randomisation may impact on the measured effectiveness.[175] Furthermore, much CAM relies upon a close client-practitioner relationship, which an RCT will normally attempt to exclude if possible. Randomised trials may be unnecessary when treatments have dramatic effects where simple observation may suffice.[176] Dramatic effects of treatments are often reported by CAM practitioners and will often form the basis of confidence for a practitioner in the efficacy of their modality based upon their own anecdotal and empirical clinical practice.

The type of procedures and modalities applied by CAM may not be easily applied to the type of approach used in relation to RCT. The use of blinding, randomisation and placebos are excluded by RCT, which avoids vital aspects of the therapeutic process.[177] Complementary and alternative medicine interventions often apply multiple modalities, therapeutic substances and procedures that do not deal well with reductionist approaches to health care preferred by OM, where a single substance is identified and applied in a controlled environment.[178] The individually focused approach preferred by CAM often applies different remedies to different persons, even if there is a similar or same illness identified based upon normal OM approaches.[179] Complementary and alternative medicine regularly involves treatment of complex, often chronic conditions and may not aim to restore balance or harmony rather than to treat any particular condition.[180]

One approach to deal with these types of methodology issues for CAM has been to consider pragmatic trials so that a whole system of healing is assessed in their context to allow highly individualised treatments involving some acknowledgement of patient views. Qualitative evidence may be used in

172 J L Wardle and E Oberg, 'The Intersecting Paradigms of Public Health and Naturopathic Medicine: Opportunities for Naturopathic Medicine' (2011) 17(11) *Jnl of Alternative and Complementary Medicine* 1079.

173 Tonelli and Callahan, above n 164, at 1214.

174 Black, above n 169, at 215.

175 Verhoef, above n 167, at 276.

176 P Glazious et al, 'When Are Randomised Trials Unnecessary? Picking Signal from Noise' (2007) 334 *British Medical Jnl* 349 at 351; Tonelli and Callahan, above n 164, at 1215.

177 Tonelli and Callahan, above n 164, at 1218.

178 Ibid.

179 J Stone and J Mathews, *Complementary Medicine and the Law*, Oxford University Press, Oxford, UK, 1996, p 13.

180 E C Webb, *Report of the Committee of Inquiry into Chiropractic, Osteopathy, Homoeopathy and Naturopathy*, Australian Government Publishing Service, Canberra, 1977, p 781.

addition to RCTs to deal with issues such as the client-practitioner relationship.[181] 'Qualitative research consists of the investigation of phenomena in their natural context, in an in-depth holistic fashion through the collection of rich narrative data'.[182] The aim of this type of research is not to provide quantified answers but to understand social phenomenon in natural settings including an understanding of practitioner/client roles and influences. If an RCT shows no treatment efficacy, it does not indicate if the intervention worked in other ways that may be unexpected. This issue is problematic, as much quantitative research may not properly deal with the context and may focus primarily on the physical to the exclusion of meaning, purpose and spirituality and will simply apply the average result.[183]

The call for RCT to provide the basis of an evidence based CAM is, in reality, a call for CAM to accept the epistemic framework of OM, which is a demand based on a philosophical view:

> By demanding that alternative medicine become evidence-based, EBM seeks to define itself not only as orthodoxy in Western Medicine, but also as the primary arbiter of all medical knowledge.[184] The alternative claim that direct observation of the individual patient remains preferable to reliance on the results of clinical trials, then, cannot simply be dismissed.[185]

Traditionally, a medical intervention is deemed successful when an intervention is effective for one individual. In the modern context, public health considerations tend to focus upon demonstrated effectiveness across a population. Randomised controlled trials do not provide the ability to determine the effectiveness of any particular intervention.[186] Randomised controlled trials do not deal well with non-measureable impacts of intervention involving a particular individual. Many CAM practices rely upon important but essentially immeasurable measures such as 'Qi' that is recognised in TCM as an invisible force which gives life to all living things.

In this sense, RCTs have difficulty in falsifying the claims of benefits by individuals. Tonelli comments:

> To prefer indirect evidence, such as that obtained from clinical trials, over primary experience represents an epistemic choice not scientific necessity. CAM and CAM practitioners, therefore, can continue to emphasize individual outcomes without inconsistency even when the therapies they utilize have failed to demonstrate efficacy in controlled clinical trials.[187]

Iyioha argues for:

> [A] regulatory system that is accommodative of different evidential paradigms. It suggests that the acceptable evidence must be that which takes into account the

181 Verhoef, above n 167, at 276.
182 Ibid.
183 Ibid, at 277–8.
184 Tonelli and Callahan, above n 164, at 1214.
185 Ibid, at 1215.
186 Ibid, at 1216.
187 Ibid.

> unique nature of CAM and advocates for a modified methodological framework, which acknowledges the belief systems and values inherent in CAM as part of the therapeutic process itself.[188]

Iyioha suggests that anthropological or ethnographic research processes may be of value in applying that type of research to determine the evidence basis for CAM to deal with factors that may not be visible from scientific methods by looking primarily at the interaction between a particular patient and a health practitioner.[189] The techniques of investigation for this type of research are through personal and intuitive patterns of knowledge. Iyioha concludes that RCTs are not designed to provide optimal research outcomes for therapies like CAM.[190] Iyioha suggests that 'science is structured to remove any human factors from the context of the study, setting up a model that is detached from feelings, meaning and subjective experiences'.[191] Since research methodologies 'are not considered to be independent from their paradigm of reference', it can be said, therefore, that 'the methods used ... for conventional medical research reflect the paradigm on which they were founded'.[192]

Other scholars have noted that the adoption of a single evidential paradigm for CAM is less than optimal. Lewith et al assert that 'no single research methodology in itself yields all the knowledge necessary with respect to effectiveness, efficacy, safety, and patient/doctor treatment preferences'.[193] Vickers affirms that the RCT indeed 'does not aim to' provide the answer to 'all questions of interest in health care'.[194] These views have prompted some scholars to demand multiple research methodologies. Is it possible to develop a pluralistic approach to research methods that retains the value of Western science for medicine and yet respects the diversity of radically different concepts about life, health and service.[195]

In addition, when scientific evidence of efficacy is provided, such as in the case of homoeopathy, it is met by a view based upon the perspective of 'prior plausibility'. Prior plausibility suggests that the lack of a plausible biological mechanism automatically invalidates the research result.[196] This view draws upon the approach that existing scientific knowledge is an adequate basis to review the quality of all health interventions, and the result from a therapy that is implausible is that it should be rejected, otherwise the basis of OM science would be overturned.[197] The view of such research is that any therapeutic result is impossible, so it must be based upon another source, ie placebo. However, 'citing biological plausibility as an explanation for accepting a lack of evidence in conventional medicine over complementary medicine is

188 Iyioha, above n 160, at 2.
189 Ibid, at 5.
190 Ibid.
191 Ibid.
192 Ibid.
193 Ibid.
194 Ibid.
195 Ibid.
196 D J Hufford, 'CAM and Cultural Diversity: Ethics and Epistemology' in Callaghan, above n 165, p 16.
197 Ibid, p 17.

flawed'.[198] 'Biological plausibility depends on contemporary biological knowledge and we should not dismiss an association because it may be new to science or medicine.'[199] Nor should traditional evidence or theories be dismissed solely because they do not fit easily within scientific concepts. For example, linguistic examination of traditional Chinese medicine concepts has suggested that traditional terminology may in fact be describing similar phenomena to scientific language, but simply expressed in a different way.[200] Reliance on current scientific evidence to judge therapies may be limiting. In 1977, the Webb report investigating regulation of naturopathy, in addition to chiropractic and osteopathy, dismissed the effectiveness of herbal medicines, suggesting that as 'the thoroughness with which the pharmaceutical industry has surveyed the global flora for pharmacologically active substances renders the probability of any significant range of effective herbal medicine most unlikely'.[201] Had this approach been taken at face value, several therapeutic agents, including the world's current gold-standard anti-malarial treatment,[202] would have been dismissed.

## Suggested model

It is not intended that this article should provide a counsel to not require an adequate evidence base for representations made about CAM. There are justified concerns expressed by many about the outrageous representations made by some unregistered health practitioners, and it is appropriate that these practices are dealt with. But regulatory theory would suggest the need to ensure proportionality and parsimony in that the measures employed are only as intrusive as is necessary to meet the regulatory objectives.[203] This may reduce the cost of enforcement as discussed above, which may not be necessary if the level of enforcement is pitched at lower levels of enforcement and results in a positive outcome for the regulatory authority. What this article does argue for is an acknowledgement that the type of evidence preferred by OM is either not obtainable for CAM for cost reasons or, if obtained, is inherently unable to deal with the nature of the modalities under consideration. This suggests a need to consider how health outcomes that need to be at the heart of any regulatory system for CAM should acknowledge the role and value of CAM. The case law has specified the cases where representations in advertising and claims made by some practitioners have been found to have breached consumer laws. In many cases, there is no evidence to support those claims. In a few cases, the quality of evidence to support claims has been deemed insufficient to provide the required level of evidence. Cases dealing with non-health therapy issues indicate that there is

198 J Margo, 'Health Science 'Turf War' Reflects Differing Approaches', *Australian Financial Review* (Sydney), 1 August 2012, p 42.

199 Ibid.

200 E S Yang et al, 'Ancient Chinese Medicine and Mechanistic Evidence of Acupuncture Physiology' (2011) (November) 462(5) *European Journal of Physiology* 645 at 646.

201 Webb, above n 180, p 9.

202 Artemisinin-based combination therapies (ACTs) derived from Qinghaosu; see also: N J White, 'Assessment of the Pharmacodynamic Properties of Antimalarial Drugs in Vivo' (1997) 41(7) *Antimicrobial Agents and Chemotherapy* 1413 at 1416.

203 A Freiberg, *The Tools of Regulation*, Federation Press, Leichhardt, NSW, 2010, p 268.

no necessity to provide scientific evidence for a representation, rather a court needs to conclude on the balance of probabilities whether there is a reasonable basis for that representation based upon expert evidence. In negligence cases against CAM practitioners, the evidence of expert CAM practitioners is accepted as influential evidence even in the face of other contrary OM expert evidence.[204] This issue arises under the claims guidelines,[205] which allow the use of traditional evidence to justify certain types of representations. A similar level of evidence should be accepted in the case of CAM advertising and representations generally and in effect apply some of the processes applied by the Australian Register of Therapeutic Goods process more widely.

In the case of advertising or representations in regard to curing or treating serious illnesses, there is a basis to argue for some limitations on representations in that circumstance requiring high quality scientific evidence.

## Conclusion

Komesaroff et al have suggested that, rather than suppressing all approaches to health care that we cannot understand or condone:

> [A] system of safeguards should be established to minimise risk, while continuing to protect the rights of consumers to choose their own health-care practices. Such safeguards should include legal, professional and conceptual criteria and target specific rogue practices while protecting and regulating others.[206]
>
> Medicine is a complex craft and much of its success depends on its ability to draw on a wide array of practices . . . We cannot afford to be overconfident about our own approaches or dismissive of those of others.[207]

The analysis above demonstrates a substantial demand for CAM in Australia. The national regulatory system for consumer protection that currently provides adequate processes to limit misleading or deceptive conduct by practitioners and manufacturers though the level of evidence required to satisfy legal tests may require reconsideration. Based upon a risk assessment for traditional evidence and different forms of scientific or professional evidence, it is possible to protect consumers and still provide them with viable health services and products that they or their practitioner determines is efficacious and safe. Within this regulatory system, it will always be necessary to have available remedies to control the activities of rogue practitioners who act contrary to professional standards as exampled in some of the cases discussed above and to apply standard professional parameters. The task is to design a regulatory system that does not allow the exploitation of vulnerable clients while allowing those who, in applying their autonomy, are entitled to explore other healthy regimes and allows manufacturers and practitioners to provide the substances and modalities that are in demand without undue regulation based upon a philosophy foreign to those choices.

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204 *Shakoor v Situ* [2000] 4 All ER 181; [2001] 1 WLR 410; *Bawden v Marin* SASC FC (1447 of 1989).

205 Department of Health and Ageing, above n 119.

206 P A Komesaroff, A Moore and I H Kerridge, 'Medicine and Science Must Oppose Intolerance and Censorship' (2012) 197 (2) *Medical Jnl of Australia* 82 at 82.

207 Ibid, at 83.